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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/628,568	07/31/2000	Leonard G. Presta	A-63470-7/DAV/JJD	6154

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EXAMINER

SAUNDERS, DAVID A

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 05/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	628,568	Applicant(s)	PRESTA
Examiner	SAUNDERS	Group Art Unit	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

Responsive to communication(s) filed on 2/18/04

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

Claim(s) 1, 21-31 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

Claim(s) 1, 21-25 is/are allowed.

Claim(s) 2, 6-31 is/are rejected.

Claim(s) _____ is/are objected to.

Claim(s) _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on _____ is approved disapproved.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ Interview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892 Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948 Other _____

Office Action Summary

Amendment of 2/18/04 has been entered. Claims 1 and 21-31 are pending and under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment and urgings have overcome previously stated bases of rejection under 35 USC 112 in the action of 8/18/03.

The examiner fails to find an electronically readable sequence listing in the file record. Full compliance with 37 CFR 1.821-1.825 is required.

Regarding the obviousness type double patenting rejection of record (action of 8/18/03), applicant 's amendment and urgings have overcome this rejection pertaining to claims 1 and 21-25. The rejection is maintained for claims 26-31 as follows:

Claims 26-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 6, 11-12 and 14 of U.S. Patent No. 6,121,022. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the basis of rejection set forth in the action of 8/18/03.

Applicant has urged that the amendment renders the double patenting rejection moot because a "salvage binding receptor taken from one loop" is not obvious over a "salvage binding receptor taken from two loops." This argument is only convincing for claims 1 and 21-25. Regarding claim 26, the examiner notes that the recited MIS and HQN sequences are taken from two different loops (see specification page 14, lines 7-9, particularly the recitation of "in another loop" at page 14, line 9). Since claim 26 recites

an epitope taken from two loops, the subject matter of claim 26 is certainly encompassed by issued claim 1, which recites "taken from two loops."

Instant dependent claims 27 and 28 have limitations shown by issued dependent claims 4 and 6, respectively; instant claims 29-31 have limitations corresponding to issued claims 11-12 and 14.

Applicant's urgings filed 2/18/04 have been considered but are unconvincing.

Applicant's amendment has necessitated the following new grounds of rejection.

Claims 26-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is overly confusing as to what the amino acid sequence is of the receptor binding epitope. Applicant must claim what is recited in a straight forward manner that recites actual sequences rather than a pile of words. Even if applicant could argue that the claim is not confusing, it is deemed that a proper sequence must be recited, in order to comply with 37 CFR 1.821-1.825.

Claims 26-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant was never in possession of the genus of salvage receptor binding epitopes having a sequence as recited in claim 26.

While the wording of claim 26 may be literally present at specification page 1+, the examiner fails to see how this describes applicant's invention, including the exemplified and most preferred species.

For example SEQ ID Nos. 1 and 2 have D at three residues C-terminal to the HQN, rather than at "two amino acids C-terminal" thereto. This also has K at two residues C-terminal to the D, rather than at "one amino acid C-terminal" thereto. Like considerations apply to the sequence shown in Fig. 2b.

Also by way of example, SEQ ID NO: 3 has T at two residues to the MIS, rather than at "one amino acid C-terminal" thereto. Like considerations apply to the sequence shown in Fig. 2a.

Preferred SEQ ID NOS. 11 and 31 do not even have either of HQN or MIS.

Given that the description of the genus set forth in claim 26 encompasses not one of the exemplified and preferred sequences, the examiner is mystified as to how applicant arrived at this description.

Claims 27 and 29-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has failed to describe the genus of "LFA-antagonists."

Specification page 11, lines 22-25 describe members of such as generally referring to an antibody directed against either CD11a or CD18 or both or to soluble

forms of ICAM-1 (e.g., the ICAM-1 extracellular domain), or to antibodies to ICAM-1, and fragments thereof, or to other molecules capable of inhibiting the interaction of LFA-1 and ICAM-1.

One of skill may reasonably envision the nature of antibodies of the recited specificities, as well as of soluble forms of ICAM-1; however one has no idea what the “other molecules” might be, and the taught antibodies and ICAM-1 fragments do not give one any guidance as to the structural features of the “other molecules”, which are merely defined by a desired functional characteristic.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is

571-272-0849. The examiner can normally be reached on Monday-Thursday from 8:00a.m to 5:30p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/tgd
May 17, 2004

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PRIMARY EXAMINER
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